REMARKS

Claims 1-7, 14-21 and 34-52 are pending in the application. Claims 1, 2 and 7 are currently amended. Claims 39-52 are new claims.

Claim Rejections – 35 U.S.C 112

Claims 1 and 2 have been amended to eliminate ambiguity by clarifying the meaning of the word "including" that was formerly recited in these claims. These amendments do not result in narrowing of the claims and merely restate what the claims previously said. Claim 7 has been amended to clarify that the necrotic tissue is provided by the action of the composition on the lesion.

Applicants respectfully traverse the rejection of claims 34-36. The Office finds that the recitation "consisting essentially of" in these claims is confusing because claim 1 recites "comprising." It is well settled that when such terms as "consisting of" or consisting essentially of" appear in a clause in the body of a claim, rather than in the preamble, the terms apply only to the clause and not to exclude other elements from the claims as a whole. *See* MPEP 2111.03; *Mannesmann Demag Corp. v. Engineered Metal Products, Inc.*, 793, F.2d 1279 ___, 230 U.S.P.Q. 45, 46, (Fed. Cir. 1986) ("[t]he district court correctly observed that the phrase "consisting of" appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause.") Thus, "consisting essentially of" applies to the corresponding elements of claims 34-36. It is not confusing to recite "consisting essentially of" in the dependant claims where there is precedent from the Federal circuit that permits both a preamble transition and a clause transition, especially where this precedent makes it clear that the clause transition applies only to the clause—in this case the body of a dependant claim. Thus, claims 34-36 may

encompass other materials that do not materially effect the basic and novel characteristics of the claimed invention.

New claims 39-52 have been added to repeat the limitations of the foregoing claims, but focusing on the combination of zinc and 8-hydroxyquinoline.

The §103 rejection of claims 1-7, 14-22 and 34-37 over EP 0 506,207 (Allen) and GB 1 215,676 (Ohmori).

Applicant respectfully traverses the Ohmori-based rejection because the Office has made an apparent error. The Office finds that page 4 of Ohmori teaches the use of zinc 8-hydroxyquinolate in concentrations up to 25% by weight. This cannot be the case where the caption of Table 1 on page 4 gives the concentrations in "mcg/ml." This means micrograms per milliliter. This is 0.000025 grams per milliliter—it is by no means 25% by weight. In an aqueous solution approximating 1 g per ml by weight, this is a concentration of 0.0025% by weight. What is claimed is a concentration of at least 5% by weight. Thus, Ohmori used the zinc 8-hydroxyquinoline in very dilute concentrations that are far below what is presently claimed—approximately 2000 times less. Ohmori used this in combination with other agents as a fungicide. There is no teaching or suggestion that the composition could have the utility of the presently claimed composition in a higher concentration.

As to Allen, the Office finds that Allen describes an equimolar zinc-containing compound that can be up to 35% zinc chloride, as is recited on page 3 at lines 23-26 of Allen. What the Office relies upon is merely a cautionary statement that zinc chloride may be escharotic in higher concentrations. Actual dosing is described in paragraph 21 on page 5. It is ascertained "by the practitioner using his ordinary skill." Also, "[d]ue to

enhanced activity which is achieved, the dosage of agent may often be decreased from that generally applicable." This is generally understood to mean, for example, 0.0000025 grams per milliliter as taught by Ohmori, and the claims recite amounts greater than 5% by weight.

The Office makes an assumption that 8-hydroxyquinoline includes all of its derivatives. The assumption is unwarranted where the claims do not recite the particular derivatives shown in Allen. What is particularly claimed is zinc 8-hydroxyquinoline, or more generally an escharotic cheatable metal agent in combination with 8-hydroxyquinoline. Allen does not teach or suggest the use of 8-hydroxyquinoline as is now claimed.

Allen's zinc chloride is used in combination with a pharmacologically active agent. These agents do not include, particularly, 8-hydroxyquinoline. By way of example, the quinoline-based pharmacologically active agents that are recited on page 4 at lines 4-7 of Allen include only "quinoline derivatives, 8-hydroxyquinoline sulfate, halogenated quinolines, 7-iodo-8-hydroxyquinoline-5-sulfonic acid, 5-chloro-7-iodo-8-hydroxyquiniline, 5-chlor-8-hydroxyquinoline, 5,7-dicholoro-8hydroxyquinoline, 5,7-diido-8-hydroxyquinoline, and decamethylene-bis (4-amino-quinaldium chloride)." See also page 15 at lines 20-23 (excluding 8-hydroxyquinioline). These materials do not encompass the use of 8-hydroxyquinoline in underrivated form.

The distinction is not trivial. The Office has noted Applicant's intention to submit a Declaration, but notes that no Declaration was provided with the last response. As can be appreciated, experiments of this nature do require some time for their completion and the experiments must be designed commensurate with a relevant showing of evidence.

The accompanying Declaration of Carl Hansen shows the results of a comparative study in which cancerous lesions were treated with comparable solutions—one containing 8-hydroxyquinoline as claimed and the other containing 8-hydroxyquinoline sulfate. The 8-hydroxyquinoline solution was effective against the lesion, while the 8-hydroxyquinoline sulfate solution was ineffective.

Allen failed to appreciate the utility of the claimed composition that is demonstrated by way of comparison in the Declaration of Carl Hansen, and as shown in the present specification. Allen merely suggested a laundry list of pharmacologically active agents that might be used as antifungals (carryover paragraph bridging pages 3-4).

In asserting this obviousness rejection, the Office has not expressly stated that the quinoline derivatives of Allen are equivalent homologs to the 8-hydroxyquinoline that is presently claimed; however, even if the materials are homologs there then, surprisingly, there is no equivalency as shown by the Declaration of Carl Hansen. This is because the quinoline homologs described by Allen, as a class, may be effective antifungals but they do not have the utility of what is claimed. This is shown by comparative evidence in the Declaration of Carl Hansen. It is a longstanding principle of patent law that even closely related chemical homologs may be separately patentable when certain of these homologs are shown to have separate utility. Discussing the patentability of chemical homologs, *In re Papesch*, 137 USPQ 43, 315 F2d 381 (CCPA 1963) says:

> The Hass and Henze cases, which are mentioned, ante- date section 103 and suggest, by way of dicta, that proof of the existence of unobvious or unexpected beneficial properties in a new compound, which would otherwise appear to be obvious (along with its properties), is indicative of the presence of "invention" and hence of patentability. What this comes down to, in final analysis, is a rather simple proposition: If that which appears, at first blush, to be obvious though new is shown by evidence not to be obvious then the evidence prevails over surmise or unsupported contention and a rejection based on obviousness must fall. Many

cases, both before and after the enactment of section 103, have been decided according to such reasoning

Therefore, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C 103.

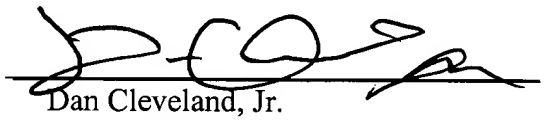
Double Patenting

As the rejection is provisional in nature, Applicants will delay the filing of a terminal disclaimer until it is necessary to do so.

The amended claims are patentable for the above reasons. No additional fees are seen to be due. However, if any additional fees are due, the Commissioner is authorized to charge them to deposit account No. 12-600.

Respectfully submitted,

LATHROP & GAGE

By: 

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